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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/668,154	09/25/2000	Kaare M. Gautvik	016777/0433	2686

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FOLEY & LARDNER  
3000 K Street NW  
Suite 500  
Washington, DC 20007

EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 12/26/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/668,154

Applicant(s)

GAUTVIK ET AL.

Examiner

Myron G. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 September 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____    | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

This office action is in response to Amendment B, paper 8, filed 9/26/02.

Claim 21 is under consideration in this office action.

***Drawings***

The formal drawings have been received; however, please see attached PTO-948.

***Response to Amendment***

**REJECTIONS WITHDRAWN**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

Claim 21 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is withdrawn because it is moot in light of the amendment.

Claim 1 was rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term "maximal response" constitutes new matter.

This rejection is withdrawn because it is moot in light of the amendment.

Claim 21 was rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not teach one that the claimed purified "hPTH" is better than synthetic hPTH.

This rejection is withdrawn because it is moot in light of the amendment.

### ***Claim Rejections - 35 USC § 102***

Claim 21 was rejected under 35 U.S.C. 102(b) as being anticipated by Olstad et al., Peptides 1994, 15 (7) 1261-1265. In making this rejection, applicant was denied the benefit of the filing dates of prior applications because the prior applications do not describe the process as was claimed.

This rejection is withdrawn because they are moot in light of the amendment.

### ***NEW REJECTIONS***

### ***Claim Rejections - 35 USC § 112***

Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim is drawn to making an intact hPTH(1- 84) in a microorganism that is reactive with antibodies against human PTH, has same molecular weight as human PTH, and migrates as a single band when run on a gel.

The specification discloses that the hormone was cleaved by a yeast protease even after the process was optimized to reduce protease cleavage. To minimize this, the sequence was mutated to make a protein that would be not cleaved by the yeast protease and therefore, make intact product (see page 15, lines 16- 26 and page 16- line 38- page 17, line 12, page 21, lines 28- 37). Furthermore, the mutant PTH was made as a fusion protein with a secretory peptide that was cleaved when secreted (Figure 6 and Example 8). Therefore, the "intact" product was not hPTH(1- 84), but a mutant variant.

There is no teaching in the specification on how to make an "intact" hPTH(1- 84). As discussed above there is teaching on how to make an intact mutant hPTH that can be expressed in yeast as a fusion protein and cleaved when secreted to become an intact but mutated hPTH. There is no teaching in the specification to what would be required to successfully express intact and unmutated hPTH(1- 84) in any microorganism and there is no teaching on how to express mutated hPTH(1- 84) in an intact form in any microorganism except yeast. There is no teaching on what mutations

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would be required and no further teaching on what mutations are similar to and reactive in the same manner as human PTH.

It is concluded that there is no reason to believe that the mutated product would be made "intact" in all microorganisms when produced by the claimed method, no guidance for protease target sites in all microorganisms, and no expectation of success in biological activity for all other changes in the hormone.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 21 is rejected under 35 U.S.C. 102(e) as being anticipated by Kronenberg et al. (US RE37919).

Kronenberg teaches a method of making hPTH(1- 84). Kronenberg fuses the hPTH(1- 84) coding sequence to a leader sequence, expresses the fusion in a microorganism, and cleaves and purifies the hPTH(1- 84). Kronenberg teaches the product has biological activities that are largely identical to a known active fragment of hPTH (Example 3) and that the product is highly pure (claims 29 and 30). Claim 21

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does not require a cleavage step but the claim is open scope so the claim may include additional steps, such as a cleavage step. Claim 21 does not require a leader sequence. The examiner understands the "intact hPTH" may include a leader sequence because of the following reason: Applicant's Example 8 is directed to the production of "intact hPTH" and this example of expression involves hPTH fused to a leader sequence. Therefore, since the only supporting disclosure of production of "intact hPTH" involves a fusion protein, the claim language is seen as encompassing expression of fusion proteins that can be cleaved to yield an "intact hPTH" product. Kronenberg is silent on electrophoresis, antibody binding, and molecular weight. Because both products are hPTH (1- 84) they would have the same molecular weight. Because the hPTH of Kronenberg has biological activity and binds cell receptors, it would also be expected to bound by anti- hPTH antibodies. Because the Kronenberg product is HPLC purified, there is reason to believe that the product is homogenous and would be one band when subjected to electrophoresis. See *In re Best*, 195 USPQ 430. Therefore, for these reasons, Kronenberg meets each and every limitation of the claim.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Myron G. Hill  
Patent Examiner  
December 23, 2002

  
**MARY E. MOSHER**  
**PRIMARY EXAMINER**  
**GROUP 1800**